

# **REMARKS**

Claims 6 – 20, 22 – 27, 29, and 47 – 53 are pending in the application. Claims 9 – 20 and 24 – 26 have been withdrawn. Claims 6 – 8, 22, 23, 27, 29, and 47 – 52 have been rejected. Claims 6 – 8, 22, 23, 27, 29, and 47 – 52 have been amended. Withdrawn claims 9 – 20 and 24 – 26 have been amended. Claim 53 is new.

No new matter has been added. Claim 53 is supported at least by Figure 3.

Reconsideration is respectfully requested.

## ***Claim Rejections - 35 USC § 102***

The Examiner has rejected claims 6 – 8 and 22 under 35 U.S.C. § 102(e) as being anticipated by Santini et al., United States Patent No. 6,656,162 (Santini).

Applicant traverses.

With respect to anticipation, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim.’ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).” Manual of Patent Examining Procedure (MPEP), 8<sup>th</sup> Edition, § 2131.

Santini does not disclose all of the elements of claim 6. First, Santini does not disclose “an attachment region within the stent surface” of a stent body “wherein the attachment region comprises a cavity in the stent surface having an open end and an opposing closed end, the cavity having a base surface at the closed end and a side wall extending from the closed end to the open end.”

The Examiner has cited FIGS. 9a – 9c to “show the medical device is a stent.” The Examiner has also cited FIG. 2A, which, in the Examiner’s view, “illustrates a substrate 210 made of metal (col. 4, lines 4, 8) that has within its surface a cavity and attachment region 220.”

The Examiner has misinterpreted the reference. Santini at column 4, lines 12 – 14 recites “FIG. 2a, for comparison, shows a ‘single’ substrate device 200, which has substrate 210, in which reservoirs 220 are filled with molecules to be released 240.” The device referred to in Santini is a microchip device which “typically include[s] a substrate having a plurality of

reservoirs containing a release system that includes the molecules to be released” (Santini, column 3, lines 33 and 34). FIGS. 9a – 9c illustrate “one embodiment of a stent-microchip drug delivery device, showing a perspective view (FIG. 9a), and two sectional views (FIGS. 9b and 9c)” (column 3, lines 11 – 13). As clearly depicted in FIG. 9a, “the microchips preferably are provided on one or more surfaces of the stent” (column 14, line 66 – column 15, line 1). Thus, the cavity cited by the Examiner is in the substrate of the microchip, and not in the surface of a stent. Santini does not disclose a cavity in the surface of a stent as claimed.

Second, the element “wherein the second porous ceramic region is less porous than the first porous ceramic region” is not disclosed in Santini. According to the Examiner, line 14 of column 12 and FIGS. 6A and 6B “illustrate that within the surface is a ceramic component,” referring to the piezoelectric material of FIGS. 6A and 6B. It is the Examiner’s view that lines 49, 50, 53, and 55 of column 8 disclose that “there is a second ceramic component . . . in the form of a cap to be on the opposite side of the first ceramic component and the attachment region on the opposing side of the first ceramic component.” The Examiner has taken the position that “[i]t can be interpreted that the second ceramic component or cap is more porous than the first ceramic component (piezoelectric element) since it is thinner.” Further elaborating, the Examiner states that “[c]eramics are known to be porous.” To support this conclusion, the Examiner has cited column 8, lines 56 – 58 of Santini, which recites “[p]referably the reservoir cap is in the form of a thin film, e.g., a film having a thickness between about 0.1  $\mu\text{m}$  and 1  $\mu\text{m}$ .”

Inherency requires that “‘the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.’ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).” MPEP, § 2112. There is nothing in the disclosure of the thickness of the cap which would necessarily require that the reservoir cap be more porous than the piezoelectric element. The fact that it may be more porous is not sufficient. “‘Inherency . . . may not be established by probabilities or possibilities. . . .’ *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).” MPEP, § 2112. Thickness does not equate to porosity. In other words, something being thinner does not mean that it is more porous.

In summary, for the above reasons, the Examiner has not met his *prima facie* burden for

showing anticipation of claim 6. Therefore, claim 6, as well as claims 7, 8, and 22 which depend from claim 6, are patentable over Santini.

### ***Claim Rejections - 35 USC § 103***

#### **First 35 U.S.C. § 103(a) Rejection**

The Examiner has rejected claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Santini in view of Alt, United States Patent No. 6,099,561 (Alt).

Claim 23 depends from claim 6. As discussed above, claim 6 is patentable over Santini. Alt does not cure the deficiencies of Santini with respect to claim 6. Therefore, claim 6, and thus also claim 23, are patentable over Santini in view of Alt.

#### **Second 35 U.S.C. § 103(a) Rejection**

The Examiner has rejected claims 27, 29, 47 – 50, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Santini in view of Brandau et al., United States Patent No. 6,709,379 (Brandau).

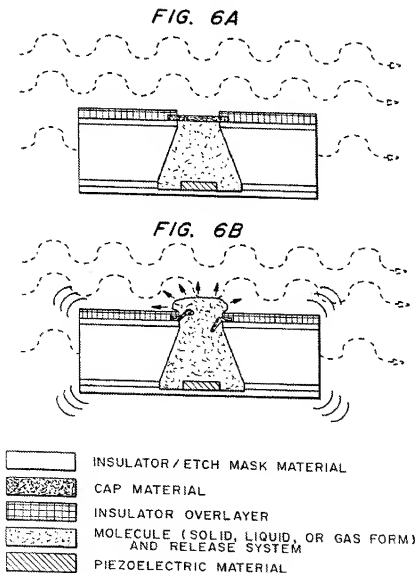
With respect to independent claim 27, it is the Examiner's view that Santini discloses all of the elements of claim 27, but "Santini does not explicitly disclose the ceramics including an oxide layer between the ceramic component and the substrate." The Examiner has cited Brandau for teaching "an oxide layer is formed for depositing layers on a substrate." Thus, according to the Examiner, "[i]t would have been obvious to one of ordinary skill in the art to utilize an oxide layer as taught by Brandau et al. with the ste[nt] of Santini et al. such that it secures the ceramic component to the substrate."

Applicant has amended claim 27 to clarify what Applicant regards as the invention.

Regardless of whether or not Brandau discloses the oxide layer as asserted by the Examiner, Santini does not disclose "an attachment region disposed within the stent surface, wherein the attachment region comprises an indentation in the stent surface." Brandau does not cure this deficiency, and thus claim 27 is patentable over Santini in view of Brandau.

In addition, Santini does not disclose "a ceramic component comprising a glass or ceramic, the ceramic component having a first porous ceramic or glass side and a second less porous ceramic or glass side, wherein the less porous ceramic or glass side of the ceramic component is fused on or within the attachment region."

It is the Examiner's position that Santini discloses all of the elements of claim 27 except the oxide layer. As noted above, the Examiner has equated the piezoelectric material in FIGS. 6A and 6B with the first porous ceramic region or side, and the cap with the second porous ceramic region or side. For clarification of the Examiner's position, Applicant has reproduced FIGS. 6A and 6B from Santini below:



With reference to FIGS. 6A and 6B, Santini states that “[u]ltrasonic waves are an alternative method capable of rupturing the cap material in order to expose the release system

and release the molecules (see FIG. 6). Actuation of piezoelectric elements on or near the reservoir produces sonic waves that rupture the cap material.” Both Figures 6A and 6B include a hatch marked feature, labeled as “piezoelectric material,” at the bottom of and in contact with the reservoir. Santini further states that “preferred piezoelectric materials are ceramics . . .” (column 12, lines 14 and 15).

With respect to the cap, Santini discloses (column 3, lines 35 – 41):

The microchip devices in some embodiments further includes one or more reservoir caps covering the reservoir openings. The reservoir caps can be designed and formed from a material which is selectively permeable to the molecules, which disintegrates to release the molecules, which ruptures to release the molecules, or a combination thereof.

Some of the materials for the cap are “metals, such as copper, gold, silver, platinum, and zinc; glasses; ceramics; semiconductors; and brittle polymers, such as semicrystalline polyesters” (column 8, lines 54 – 56).

Regarding the reservoir, “[t]he molecules to be delivered may be inserted into the reservoirs in their pure form, as a liquid solution or gel, or they may be encapsulated within or by a release system,” where the “‘release system’ includes both the situation where the molecules are in pure form, as either a solid or liquid, or are in a matrix formed of degradable material or a material which releases incorporated molecules by diffusion out of or disintegration of the matrix.”

In summary, FIG. 6A illustrates the piezoelectric material at the bottom of the reservoir with an intact cap over the reservoir. Once the piezoelectric material is actuated, creating sonic waves, the cap is broken, releasing the molecules in the reservoir as depicted in FIG. 6B.

As best understood by Applicant, the Examiner has interpreted the combination of the piezoelectric material, the reservoir, presumably filled with molecules to be released, and the cap, as comprising the “ceramic component” of Applicant’s claim 27. Such an interpretation is clearly erroneous. Although pending claims “must be ‘given their broadest reasonable interpretation consistent with the specification’” (citations omitted), “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999).” MPEP, § 2111.01.

Santini clearly refers to the piezoelectric elements and the reservoir caps as separate components. A side may be defined as “a line or surface forming a border or face of an object (a die has six sides)” (Merriam-Webster’s on-line dictionary). One of skill in the art would not have interpreted the reservoir cap as “a first porous ceramic or glass side,” and the piezoelectric element as “a second less porous ceramic or glass side” of a ceramic component. Additionally, the space between the two “sides” is the reservoir, and the reservoirs are described as “filled with molecules to be released” (column 4, lines 13 and 14). Such an interpretation means that the ceramic component would comprise the piezoelectric element, the reservoir cap, and the reservoir, presumably filled with a substance. There is nothing in Santini that discloses, suggests, or hints that the piezoelectric element and reservoir cap be regarded opposite “sides” of a single larger component. Clearly, the Examiner’s interpretation of Santini is unreasonable.

Claim 29 depends from claim 27, and is therefore patentable for at least the same reasons that claim 27 is patentable.

Claims 47 – 50 and 52 depend from claim 6. As noted above, claim 6 is patentable over Santini. Brandau does not cure the deficiencies of Santini with respect to claim 6. Therefore, claims 47 – 50 and 52 are patentable over Santini in view of Brandau.

#### Third 35 U.S.C. § 103(a) Rejection

The Examiner has rejected claim 51 under 35 U.S.C. § 103(a) as being unpatentable over Santini in view of Pope et al., United States Patent No. 6,290,726 (Pope).

Claim 51 depends from claim 6. It is the Examiner’s position that Santini discloses the elements of claim 6, but Santini does not “disclose the specific ceramic material being quartz.” Thus, the Examiner has cited Pope for the teaching that “a quartz ceramic can be used in the body for prostheses for low friction and long life, col. 11, lines 10 – 12, 35, 36.”

As noted above Santini does not disclose all the elements of claim 6. Even if Pope discloses the use of quartz in prostheses, Pope does not cure the deficiencies of Santini with respect to claim 6. Thus, claim 6 and claim 51, that depends from claim 6, are patentable over the combination of Santini in view of Pope.

***Rejoinder***

As Applicant respectfully submits that the pending claims are in condition for allowance, Applicant requests rejoinder of withdrawn claims 9 – 20 and 24 – 26 under MPEP § 821.04 which recites:

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits.

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim.

**Conclusion**

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance. Applicant respectfully requests the allowance of pending claims 6 – 8, 22, 23, 27, 29, and 47 – 53, and rejoinder with subsequent examination on the merits of claims 9 – 20 and 24 – 26.

If necessary to ensure a timely response, this paper should be considered as a petition for an Extension of Time sufficient to provide a timely response. The undersigned authorizes the Commissioner to charge any fees that may be required, or credit of any overpayment to be made, to the **Squire, Sanders, and Dempsey Deposit Account No. 07-1850**.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

Dated: October 5, 2009  
Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111-3492  
Telephone (415) 954-0397 (direct)  
Telephone (415) 954-0200  
Facsimile (415) 393-9887

By /Gloria M. Gusler, Reg. No. 50,282/  
Gloria M. Gusler, Ph.D.  
Attorney for Applicant  
Reg. No. 50,282